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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/790,224 | 03/02/2004 | Yumi Matsuzaki | US-162 | 9934 |

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| EXAMINER |
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ODELL, LINDSAY T

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| ART UNIT | PAPER NUMBER |
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1652

DATE MAILED: 04/21/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/790,224

Applicant(s)

MATSUZAKI ET AL.

Examiner

Lindsay Odell

Art Unit

1652

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 March 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-10 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

[Handwritten signature]

DETAILED ACTION

Application Status

1. In response to the previous Office action, a written restriction requirement (mailed on February 24, 2005), Applicants filed a response received on March 18, 2005. Applicant's election, without traverse, of Group I, Claims 2, 3, and 4, in the reply filed on March 18, 2005 is acknowledged. The instant Office action is a supplemental restriction requirement that better groups the instant claims; said action is the second supplemental restriction requirement. Said supplemental requirement is at the discretion of the Examiner (see M.P.E.P. § 802 and 37 C.F.R. § 1.142) and is deemed appropriate and necessary in view of the complex subject matter of the instant claims and the extensive searching required to identify prior art relating to the instant subject matter. Claims 1-10 are pending.

Restriction

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:
- I. Claims 3 and 4, drawn to a coryneform bacterium wherein glutamine synthetase activity is enhanced by mutating the adenylation site of glutamine synthetase, classified in class 435, subclass 252.1.
 - II. Claims 3 and 5, drawn to a coryneform bacterium wherein glutamine synthetase activity is enhanced by reducing the intracellular activity of glutamine synthetase adenylyltransferase (ATase), classified in class 435, subclass 252.1.

Art Unit: 1652

- III. Claim 3, drawn to a coryneform bacterium wherein glutamine synthetase activity is enhanced by reducing the intracellular activity of II protein, classified in class 435, subclass 252.1.
- IV.. Claims 3, 6, and 7, drawn to a coryneform bacterium wherein glutamine synthetase activity is enhanced by modifying a nitrogen metabolism regulation protein, classified in class 435, subclass 252.1.
- V. Claim 10, drawn to a method for producing L-arginine or L-lysine, classified in class 435, subclass 106.

3. Claims 1-2 and 8-9 link(s) inventions I-IV. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claims 1-2 and 8-9. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Art Unit: 1652

4. The inventions are distinct, each from the other because of the following reasons:

The bacteria of Groups I through IV are related to each other because they all have enhanced glutamine synthetase activity due to a reduction in the adenylation of glutamine synthetase. Although each of Groups I-IV are related to each other, they are distinct inventions because they all have different functional and structural features. For example, the bacteria of Group I have structural alterations of glutamine synthetase, an enzyme that functions in glutamine synthesis; the bacteria of Group II have alterations to the activity of ATase, an enzyme that adenylylates glutamine synthetase; the bacteria of Group III have alterations to the activity of PII protein, a protein involved in adenylation of glutamine synthetase by ATase; and the bacteria of Group IV have structural alterations to a nitrogen metabolism regulation protein, which functions in nitrogen metabolism. Thus, Groups I-IV are patentably distinct, each from the other, because they have distinct structural and functional characteristics. In addition, the search of textual databases for each of the Groups is different because the proteins and enzymes affected in the bacteria of each of the Groups are distinct. A search of the bacteria of the Groups requires that the sequences of the proteins and enzymes affected in the bacteria be searched in commercial amino acid sequence databases, for example SEQ ID NO: 20. The proteins and enzymes affected in the bacteria of each of the Groups have wholly different amino acid sequences from those of the other Groups. Therefore, a different search in commercial amino acid sequence databases is required for the claims in each Group than is required for the claims in the other Groups. To search each of Groups I-IV with each other would present a search burden on the Office because the searches in both textual databases and in commercial amino acid sequence databases are not co-extensive. Thus, Groups I-IV have been appropriately

Art Unit: 1652

restricted from each other on the basis of being both independent or distinct, and presenting a search burden on the Office if they were to be searched together.

Groups I and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the method of Group V can be practiced with the bacteria of Groups II-IV. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper. Thus, Group I has been appropriately restricted from Group V on the basis of being both independent or distinct, and presenting a search burden on the Office if they were to be searched together.

Groups II and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the method of Group V can be practiced with the bacteria of Groups I, III and IV. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper. Thus, Group II has been appropriately restricted from Group V on the basis of being both independent or distinct, and presenting a search burden on the Office if they were to be searched together.

Art Unit: 1652

Groups III and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the method of Group V can be practiced with the bacteria of Groups I, II and IV. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper. Thus, Group III has been appropriately restricted from Group V on the basis of being both independent or distinct, and presenting a search burden on the Office if they were to be searched together.

Groups IV and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the method of Group V can be practiced with the bacteria of Groups I-III. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper. Thus, Group IV has been appropriately restricted from Group V on the basis of being both independent or distinct, and presenting a search burden on the Office if they were to be searched together.

Notice of Possible Rejoinder

5. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so**

Art Unit: 1652

may result in a loss of the right to rejoinder. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Election

6. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Conclusion

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lindsay Odell whose telephone number is 571-272-3445. The examiner can normally be reached on M-F, 8:00-4:30.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy can be reached on 571-272-0928. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Art Unit: 1652

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Lindsay Odell, Ph.D.
April 15, 2005


KATHLEEN KERR, PH.D.
PRIMARY EXAMINER